ORIGINAL

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

- - - - - - - - - - - - - - - - - - - -X

KENNETH DUNHAM and MARTHA DUNHAM,

Plaintiffs,

- against -

COVIDIEN LP,

Defendant.

- - - - - - - - - - - - - - - - - - - -X

19 Civ. 2851 (LLS)

OPINION & ORDER

In this medical device product liability action, defendant Covidien LP moves to dismiss plaintiffs Kenneth and Martha Dunham's first amended complaint ("FAC") (Dkt. No. 16) pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). For the following reasons, the motion (Dkt. No. 17) is granted in part and denied in part.

BACKGROUND

Plaintiffs Kenneth and Martha Dunham brought this action to recover for alleged injuries related to Mr. Dunham's use of Covidien's hernia mesh products. Compl. (Dkt. No. 3-1). On May 22, 2019, this Court granted Covidien's motion to dismiss the complaint, but granted the Dunhams leave to amend the complaint within 45 days. On July 3, the Dunhams filed the FAC, which Covidien has now moved to dismiss.

The facts of the FAC are substantially the same as those in the original complaint, with the following relevant additions:

- "Once the collagen barrier dissolves, it leaves the internal organs unprotected and increases the chances of adhesions, inflammatory response to the polyester, and formation of devastating scar tissue." FAC ¶¶ 55, 83, 142-43, 177-78.

- "Further, heavyweight small-pore meshes may withstand greater forces of scar contraction than large-pore lightweight meshes and may exhibit less shrinkage. This is a large-pore mesh, prone to contraction and shrinkage." Id. ¶¶ 144-45, 179-80.

- "The defective design was a proximate cause of Plaintiff's injuries as it did not strengthen the surrounding scar tissue, which lead to multiple recurrences, as well as nerve endings growing [into] pores of the lightweight, macroporous mesh, causing debilitating pain." Id. ¶¶ 159, 199, 208, 252.

- Specification of the "serious bodily injuries" that Mr. Dunham suffered as "including constant abdominal pain, scar tissue, and recurrent hernias." Id. ¶¶ 125, 213, 229, 243, 254, 268, 275, 286, 312, 320.

- Addition of alternative designs, including "a heavyweight small-pore mesh design. Further, a flat mesh and/or non-woven mesh are feasible alternatives that are less dangerous, equally effective and economically feasible." Id. ¶¶ 154, 194.

- "Specifically, Defendant completely failed to warn about the fact that as the collagen erodes, it increases the likelihood of adhesion formation, the formation of debilitating scar tissue, and the bodies [sic] likelihood of an inflammatory response to the polyester material. Defendant failed to warn about the high likelihood of mesh shrinkage, contraction, and migration, which are side effects of the large-pore meshes such as this one." Id. ¶¶ 219-20, 233-34, 333-34.

- "The Defendant's failure to adequately warn Plaintiff and/or his physicians and/or the medical community of these risks lead to the Plaintiff being implanted with this mesh, which has failed, causing him to suffer constant pain, scar tissue and recurrent hernias, which were not properly warned of." Id. ¶ 253.

- "Defendants breached their duty through the failure to properly research and design the mesh product through its failure to use a non-woven or flat mesh to eliminate pores which nerves can grow into." Id. ¶ 249.

- "These warranties ["eliminates the pain associated with traditional tax [sic] fixation," "low post-operative pain and fast recovery in laparoscopic inguinal hernia repairs," "easy to use"] were in fact, false. Specifically, the mesh did not eliminate the pain of fixation, or the post-operative pain. Plaintiff still has pain in the abdomen around or near the site of the implant caused by the micro-grips used on the mesh to secure it and/or nerve endings growing into the woven pores of the mesh." Id. ¶¶ 259-61.

- "Specifically, the mesh was not reliable, nor was it a hernia repair solution as the Plaintiff has had recurring hernias, constant pain and scar tissue since the mesh was implanted." Id. ¶ 264.

- "Defendant materially misrepresented to the medical community, potential plaintiffs and Plaintiff alike, the effectiveness of the mesh without representing the potential for failure, bacteria, adhesions, contraction and shrinkage. Defendant made material misrepresentations as to the amount of pain those implanted with the meshes would feel. Defendant specifically warranted and represented that those implanted with the Parietex™ / Progrip™ meshes that there would be less post operative pain, as well as less pain from fixation." Id. ¶¶ 279-81.

DISCUSSION[1]

Strict Liability and Negligence Claims[2]

Defective Manufacture To state a defective manufacture claim under New York law, a plaintiff must state facts plausibly alleging "that (1) the product was defective due to an error in the manufacturing process and (2) the defect was the proximate cause of plaintiff's injury." Williamson v. Stryker Corp., No. 12 Civ. 7083, 2013 WL 3833081, at *4 (S.D.N.Y. July 23, 2013). "[A] plaintiff may rely upon the circumstances of an accident to prove the existence of a manufacturing defect if the product did not perform as intended and the possibility of other causes has been excluded." Id. at *5.

The FAC seeks to support Mr. Dunham's manufacturing defect claim by adding factual content to three sentences. See FAC ¶¶ 55, 83, & 125. This content, however, is mostly redundant. The one new factual allegation in the FAC's manufacturing defect claim speaks only to the causal connection between collagen dissolution and some of the dangers associated with polyester surgical mesh. See FAC ¶¶ 55, 83. ("Once the collagen barrier

---

[1] Except where otherwise stated, the allegations discussed in this opinion refer to both the ProGrip and Parietex meshes.

[2] "New York courts generally consider strict products liability and negligence claims to be functionally synonymous." S.F. v. Archer Daniels Midland Co., 594 F. App'x 11, 12 (2d Cir. 2014). Accordingly, Mr. Dunham's strict liability and negligence claims are analyzed concurrently.

dissolves, it leaves the internal organs unprotected and increases the chances of adhesions, inflammatory response to the polyester, and formation of devastating scar tissue."). Because the FAC does not state any facts plausibly alleging either a manufacturing defect or the exclusion of other possible causes of Mr. Dunham's injuries, his defective manufacture claim fails.

Defective Design To state a design defect claim, a plaintiff must allege that: "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing the plaintiff's injury." Kennedy v. Covidien, LP, No. 118 Civ. 1907, 2019 WL 1429979, at *3 (S.D.N.Y. Mar. 29, 2019).

The FAC adds considerable factual content supporting its allegation of a design defect. Unlike the original complaint, the FAC "allege[s] how the collagen film mitigates or fails to mitigate detached polyester's harmful effects," id., by alleging that, "Once the collagen barrier dissolves, it leaves the internal organs unprotected and increases the chances of adhesions, inflammatory response to the polyester, and formation of devastating scar tissue." FAC ¶¶ 55, 83, 142-43, 177-78. This alleges both causation and likelihood of harm.

The FAC also alleges that the meshes' design was both defective and the proximate cause of Mr. Dunham's injuries, "as it did not strengthen the surrounding scar tissue, which lead to multiple recurrences, as well as nerve endings growing [into] pores of the lightweight, macroporous mesh, causing debilitating pain." Id. ¶¶ 159, 199, 208; see also id. ¶¶ 145, 180 ("This is a large-pore mesh, prone to contraction and shrinkage.").

The FAC also sufficiently alleges an alternative design for the mesh. It claims that "heavyweight small-pore meshes may withstand greater forces of scar contraction than large-pore lightweight meshes and may exhibit less shrinkage." Id. ¶¶ 144-45, 179-80; see also id. ¶¶ 154, 194. It also claims that "a flat mesh and/or non-woven mesh are feasible alternatives that are less dangerous, equally effective and economically feasible." Id. ¶¶ 154, 194. Thus, Mr. Dunham's defective design claim survives Covidien's motion to dismiss.

Failure to Warn "A manufacturer has a duty to warn against latent dangers resulting from foreseeable uses of its product of which it knew or should have known." Liriano v. Hobart Corp., 92 N.Y.2d 232, 237, 700 N.E.2d 303, 305 (1998). To state a failure to warn claim, a plaintiff must state facts plausibly alleging the breach of such a duty, as well as that said breach was the proximate cause of the plaintiff's alleged injuries.

See State Farm Fire & Cas. Co. v. Nutone, Inc., 426 F. App'x 8, 10 (2d Cir. 2011) (citing Liriano, 92 N.Y.2d at 237, 700 N.E.2d at 305).

The FAC alleges that Covidien's mesh products were implanted in Mr. Dunham for their intended purpose -- to "repair hernias through reinforcement." FAC ¶¶ 222, 237. The FAC also alleges that Covidien failed to warn Mr. Dunham that: (1) collagen erosion in Covidien's mesh products increases the likelihood of adhesion, scarring, and inflammation, see id. ¶¶ 219, 233; and (2) large pore meshes, like those manufactured by Covidien and used by Mr. Dunham, let nerves grow through their pores and have a high likelihood of mesh shrinkage, contraction, and migration, resulting in debilitating pain, see id. ¶¶ 159, 199, 208, 220, 234. The FAC also alleges that Mr. Dunham's physicians would not have used defendant's Progrip or Parietex mesh "had it been equipped with sufficient warnings, including the possibility for mesh migration, failure, chronic pain, and the need for future surgeries." Id. ¶¶ 228, 242. These adequately allege proximate cause.[3] Thus, the FAC states a failure to warn claim.

---

[3] New York uses an informed intermediary doctrine, whereby warnings must be given to "the physician, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects." . . . Insofar as

However, Covidien attached the ProGrip mesh's Instructions for Use ("IFU") to its motion to dismiss the FAC (Dkt. No. 18-1), arguing that they "warn about the very complications Plaintiff Kenneth Dunham allegedly suffered: pain, adhesions and hernia recurrence . . . ." Dkt. No. 18, at 12.[4] "Generally, consideration of a motion to dismiss under Rule 12(b)(6) is limited to consideration of the complaint itself. Faulkner v. Beer, 463 F.3d 130, 134 (2d Cir. 2006). However, "Consideration of materials outside the complaint is not entirely foreclosed on a 12(b)(6) motion." Id., 463 F.3d at 134.

> [. . .] when a plaintiff chooses not to attach to the complaint or incorporate by reference a prospectus upon which it solely relies and which is integral to the complaint, the defendant may produce the prospectus when attacking the complaint for its failure to state a claim, because plaintiff should not so easily be allowed to escape the consequences of its own failure.

---

adequate warnings are concerned, under New York law, "[i]f the doctor is sufficiently warned, the product is not defective."

Tomaselli v. N.Y. & Presbyterian Hosp., 728 F. App'x 41, 43 (2d Cir. 2018) (alteration in original) (first quoting Martin v. Hacker, 83 N.Y.2d 1, 9, 628 N.E.2d 1308, 1311 (1993); then quoting Fane v. Zimmer, Inc., 927 F.2d 124, 129 (2d Cir. 1991)).

[4] Covidien submitted only the ProGrip IFU, arguing that while the Dunhams include information in their FAC regarding Parietex Optimized Composite ("PCOx") mesh, they do not allege that Mr. Dunham was implanted with PCOx mesh, but rather an "unspecified type" of Parietex mesh. However, the FAC uses the terms PCOx and Parietex interchangeably and includes a specific lot number for the Parietex mesh it alleges was implanted into Mr. Dunham. FAC ¶ 106. Because Covidien provided only the ProGrip IFU, this part of the analysis applies only to the ProGrip claims.

Cortec Indus., Inc. v. Sum Holding L.P., 949 F.2d 42, 47-48 (2d Cir. 1991), cert. denied, 503 U.S. 960 (1992).

> However, before materials outside the record may become the basis for a dismissal, several conditions must be met. For example, even if a document is "integral" to the complaint, it must be clear on the record that no dispute exists regarding the authenticity or accuracy of the document. It must also be clear that there exist no material disputed issues of fact regarding the relevance of the document.

Faulkner, 463 F.3d at 134 (citations omitted).

As the ProGrip IFU is the very document that gives doctors the warnings that the FAC claims were insufficient, it is integral to the FAC. And as Covidien attached the IFU to both of its motions to dismiss, Mr. Dunham has been on notice of the IFU since, at latest, April 11, 2019, when his attorney filed her notice of appearance. Because Mr. Dunham has not challenged the authenticity, accuracy, or relevance of the IFU in any of his filings since then, including his oppositions to both motions to dismiss and the FAC itself, this Court will consider the IFU in determining whether to dismiss the FAC.

The ProGrip IFU begins in bold, all-capital letters, "BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY," followed by "IMPORTANT!" The "CONTRAINDICATIONS" section states "The collagen film is not intended to minimize tissue attachment[ ] . . . ." The "POSSIBLE COMPLICATIONS"

section includes "seroma, hematoma, recurrence, inflammation, chronic pain, infection, allergic reactions to the components of the product." Finally, the "WARNINGS" section states "To avoid injury, careful attention is required if fixating the device in the presence of nerves or vessels," and addresses the risk of recurrence, stating "To limit the risk of recurrence, excessive tension should be avoided on the ProGrip™ laparoscopic self-fixating mesh and on the fixation points if any, to account for wound shrinkage during the healing process."

The "POSSIBLE COMPLICATIONS" section alone warns of all the injuries Mr. Dunham alleges he incurred and Covidien failed to warn him and his doctors about: adhesion/tissue attachment, inflammation, chronic pain, nerve damage. Thus, Mr. Dunham's failure to warn claim about the ProGrip mesh is dismissed as implausible, while his similar claim about the Parietex mesh survives Covidien's motion to dismiss.

Negligent Misrepresentation To state a claim for negligent misrepresentation, a plaintiff must state facts plausibly alleging "(1) the existence of a special or privity-like relationship imposing a duty on the defendant to impart correct information to the plaintiff; (2) that the information was incorrect; and (3) reasonable reliance on the information." J.A.O. Acquisition Corp. v. Stavitsky, 8 N.Y.3d 144, 148, 863

N.E.2d 585, 587 (2007). The three factors relevant to whether a special relationship giving rise to a duty exists are "whether the person making the representation held or appeared to hold unique or special expertise; whether a special relationship of trust or confidence existed between the parties; and whether the speaker was aware of the use to which the information would be put and supplied it for that purpose." Williamson, 2013 WL 3833081, at *11.

The FAC alleges that, as a medical device company holding its products out to patients and doctors as safe and effective for their intended use in hernia repairs, Covidien had a duty to patients who used its products. See FAC ¶¶ 272, 277-78. The FAC further alleges that Covidien breached this duty by misrepresenting "the amount of pain those implanted with the meshes would feel," id. ¶ 280, and "the effectiveness of the mesh without representing the potential for failure, bacteria, adhesions, contraction and shrinkage," id. ¶ 279. The FAC also alleges that Mr. Dunham and his physician "reasonably relied upon Defendant's misrepresentations and omissions regarding the safety and efficacy of Defendant's hernia mesh products, resulting in Plaintiffs sustaining permanent personal injuries

and damages." Id. ¶ 303. Thus, the FAC states a claim for negligent misrepresentation under Rule 8(a).[5]

Fraud Claims

Fraudulent Misrepresentation

Rule 9(b), which applies to fraudulent misrepresentation claims, "requires that the plaintiff (1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." Fin. Guar. Ins. Co. v. Putnam Advisory Co., 783 F.3d 395, 403 (2d Cir. 2015). Within the FAC's fraudulent misrepresentation claim, the only specific statements claimed to be false and misleading are in paragraphs 288 and 289. Paragraph 288 describes the device as "Leading the future of fixation, self fixating, less pain, easy to use and lower costs," and 289 describes it as providing "easy deployment and fixation," and supporting "tissue integration while minimizing visceral attachment with collagen film." These statements are too general to be susceptible to attack as

[5] While Rule 9(b) applies to negligent misrepresentation claims that sound in fraud, Matsumura v. Benihana Nat. Corp., 542 F. Supp. 2d 245, 251-52 (S.D.N.Y. 2008), Rule 8(a) applies to those that sound in "ordinary negligence," see Woori Bank v. RBS Securities, Inc., 910 F.Supp.2d 697, 705 (S.D.N.Y. 2012).

fraudulent, in stark contrast to the specific charges made in the defective design and failure to warn sections above. Outside the fraudulent misrepresentation claim, in the FAC at large, the many misrepresentations discussed above are made repeatedly, but not in a form which complies with Rule 9(b). Thus, the FAC's fraudulent misrepresentation claim fails.

Consumer Fraud - §§ 349, 350 of the New York General Business Law Under both Sections 349 (prohibiting deceptive acts and practices) and 350 (prohibiting false advertising), a complaint must plausibly allege that the defendant engaged in "(1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice." Orlander v. Staples, Inc., 802 F.3d 289, 300 (2d Cir. 2015). "Omissions, as well as acts, may form the basis of" a claim brought under either Section 349, In re Evergreen Mut. Funds Fee Litig., 423 F. Supp. 2d 249, 264 (S.D.N.Y. 2006), or 350, see NYGBL § 350-a(1).

The FAC alleges two problems with Covidien's mesh products about which Covidien failed to warn consumers, resulting in Mr. Dunham's injuries: (1) collagen erosion increasing the likelihood of adhesion, scarring, and inflammation, FAC ¶ 333; and (2) large pore meshes, like those at issue here, letting nerves grow through their pores and having a high likelihood of

shrinkage, contraction, and migration, resulting in debilitating pain, FAC ¶ 344. While the FAC, in isolation, states Section 349 and 350 claims, for the reasons discussed with regard to the ProGrip IFU defeating the FAC's failure to warn claim, the FAC's Section 349 and 350 claims about the ProGrip mesh are dismissed as implausible, while its similar claims about the Parietex mesh survive Covidien's motion to dismiss.

Breach of Warranty Claims

Express Warranty "A breach of express warranty claim require[s] a plaintiff to plead some affirmative statement of fact that forms the basis of the warranty. The statement must be definite enough so that its natural tendency [is] ... to induce the buyer to purchase." Becker v. Cephalon, Inc., No. 14 Civ. 3864, 2015 WL 5472311, at *7 (S.D.N.Y. Sept. 15, 2015) (alterations in original) (internal quotation marks omitted).

Of the statements alleged to be warranties in the FAC, only one is definite: that ProGrip mesh "eliminates the pain associated with traditional tax fixation." FAC ¶ 258. However, the FAC does not identify where this statement was made. Even if that statement is a warranty, the ProGrip IFU's warning that "chronic pain" is one of "[t]he possible complications associated with the use of ProGrip™ laparoscopic self-fixating

mesh . . . ," Dkt. No. 18-1, at 2, effectively disclaims it. See Riegel v. Medtronic, Inc., No. 99 Civ. 0649, 2003 WL 25556778, at *2-3 (S.D.N.Y. Dec. 3, 2003). Thus, the FAC's express warranty claim fails as a matter of law.

Implied Warranty A claim for breach of implied warranty in a products liability action must state facts plausibly alleging that, when it left defendant's possession, the product was defective -- that it was not "fit for the ordinary purposes for which such goods are used." Denny v. Ford Motor Co., 87 N.Y.2d 248, 258, 662 N.E.2d 730, 736 (1995). "The defect may arise from a manufacturing flaw, improper design, or a failure to provide adequate warnings regarding use of the product . . . ." DiBartolo v. Abbott Labs., 914 F. Supp. 2d 601, 627 (S.D.N.Y. 2012) (internal quotation marks omitted). For the reasons stated regarding the strict liability and negligence claims above, the FAC states a claim for breach of implied warranty with regard to both meshes' defective design and the Parietex mesh's failure to warn.

Remaining Claims

Unjust Enrichment "An unjust enrichment claim is not available where it simply duplicates, or replaces, a conventional contract or tort claim." Corsello v. Verizon N.Y.,

Inc., 18 N.Y.3d 777, 790, 967 N.E.2d 1177, 1185 (2012). As the FAC's unjust enrichment claim does just that, it fails as a matter of law.

Loss of Consortium As loss of consortium is a derivative claim, Mrs. Dunham's loss of consortium claims survive only to the extent that Mr. Dunham's claims do. See Cordova v. Smith & Nephew, Inc., No. 14 Civ. 351, 2014 WL 3749421, at *9 (E.D.N.Y. July 30, 2014).

CONCLUSION

Covidien's motion to dismiss (Dkt. No. 17) is granted as to Mr. Dunham's claims for defective manufacture, failure to warn about the ProGrip mesh, fraudulent misrepresentation, consumer fraud under NYGBL §§ 349 and 350 as to the ProGrip mesh, and breach of express warranty, as well as Mrs. Dunham's claims for loss of consortium derived from any of those claims. It is denied as to Mr. Dunham's claims for defective design, failure to warn about the Parietex mesh, negligent misrepresentation, consumer fraud under NYGBL §§ 349 and 350 as to the Parietex mesh, and breach of implied warranty with regard to both meshes' defective design and the Parietex mesh's failure to warn, as

well as Mrs. Dunham's claims for loss of consortium derived from any of those claims.

So ordered.

Dated: November 27, 2019
New York, New York

Louis L. Stanton

LOUIS L. STANTON
U.S.D.J.